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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,670	08/27/2001	Jens Petersen	60117.000007	2509

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EXAMINER

ISABELLA, DAVID J

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 06/05/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/938,670

Applicant(s)

PETERSEN, ET AL

Examiner

DAVID J ISABELLA

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 13-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6. 6) ☐ Other: _____

Election/Restrictions

Claims 13-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

Applicant's election with traverse of claims 1-12 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that there is no evidence that the hydrogel is useful as a moisturizer. This is not found persuasive because it is well known that hydrogels are used in the manufacturing of moisturizers. Clearly the scope of the prosthesis of claim 12 including a silicone based housing and the pyrogen free water is not required by the composition of claim 1.

With respect to group III, the composition of group I does not require the step of combining acrylamide and methylene bis-acrylamide using radical initiation.

Similarly, the various methods and surgical treatment do not require the specifics of the composition of group I nor the specifics of the method for making the composition of group III.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. These

claims are omnibus type claims. Claims 1-3 fail to positively set forth the composition of the hydrogel. The recitation of less than 3.5% encompasses 0%. If the claims have 0% polyacrylamide, then the claims are directed to a biocompatible hydrogel. The specification cannot possibly support the infinite species of hydrogels.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite for failing to positively claim the composition of the hydrogel. Recitation of "obtainable" fails to positively limit the same.

Claims 2-4, it is not clear what parameters the 95% encompasses (ie 95% of what?).

Claims 6,7, what is a "complex viscosity". Is the viscosity based on the hydrogel or some subcombination thereof?

Claim 10 as worded is confusing. It is not clear as to what is being claimed. What is meant by "to such a degree so as to have an efficient"?

Claim 12 is indefinite. The preamble of the claim is directed to a hydrogel yet the body of the claim attempts to further define an endoprosthesis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 3738

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over USSR Inventor's certificate 1697756 as referenced in Pavlyk (5798096).

According to the disclosure of Pavlyk, the hydrogel of the USSR Inventor's certificate contains 3% by weight of polyacrylamide in pyrogen-free water. In so far as the claims are definite, it appears that the claims fail to define over the hydrogel of the USSR Inventor's certificate 1697756.

Claims 4-9 are directed to the physical properties of the hydrogel. Examiner contends that since the composition of the hydrogel is the same as claimed, then the properties, including the viscosity and the elastic modulus, would be within the range as claimed.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-12 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lopatine, et al (WO 01/49336).

Lopatine, et al discloses a biocompatible hydrogel containing cross linked copolymers of acrylamide and methylene bis-acrylamide in a molar ratio within the range as claimed by applicant.

The crosslinked copolymer comprises between 2-15% of the hydrogel by total weight.

Claims 4-11 are directed to the physical properties of the hydrogel. Examiner contends that since the composition of the hydrogel is the same as claimed, then the properties, including the viscosity and the elastic modulus, would be within the range as claimed.


Claim 12, see page 1, lines 10+.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J ISABELLA whose telephone number is 703-308-3060. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3579 for regular communications and 703-305-3580 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



DAVID J ISABELLA
Primary Examiner
Art Unit 3738

dji
June 2, 2003